Herbalife International of America, Inc.

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21491 John Venardos Vice President Regulatory & Government Affairs

August 9, 2002

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Office of Nutritional Products Labeling and Dietary Supplements FOOD & DRUG ADMINISTRATION 200 C Street, S.W. Washington, D.C. 20204

Ref: K8 Tablets

Dear Sir and/or Madam:

Pursuant to 21 CFR 101.93, please be advised that Herbalife International of America, Inc. has revised labeling for our K8 dietary supplement tablets to revise cautionary wording appearing on the label as developed by industry in consultation with the agency. The complete K8 label is attached.

K8 tablets are labeled and promoted with statements provided for in section 403(r)(6) of the Federal Food, Drug and Cosmetic Act:

## LABEL

(Note: Immediately adjacent to the following copy, appears a ruled DSHEA disclaimer box.) K8 is a combination of natural herbs, including Kava Kava and ashwagandha, as well as Calcium and is designed to help relax the body while contributing to a sense of well-being.

Directly beneath the ruled disclaimer box appears the following cautionary wording:

CAUTION: THE US FDA ADVISES THAT A POTENTIAL RISK OF RARE, BUT SEVERE, LIVER INJURY MAY BE ASSOCIATED WITH KAVA-CONTAINING DIETARY SUPPLEMENTS. ASK A HEALTH CARE PROFESSIONAL BEFORE USE IF YOU HAVE OR HAVE HAD LIVER PROBLEMS, FREQUENTLY USE ALCOHOLIC BEVERAGES, OR ARE TAKING ANY MEDICATION. STOP USE AND SEE A DOCTOR IF YOU DEVELOP SYMPTOMS THAT MAY SIGNAL LIVER PROBLEMS INCLUDING JAUNDICE (YELLOWING OF THE SKIN OR WHITES OF THE EYES) AND BROWN URINE. OTHER NONSPECIFIC SYMPTOMS CAN INCLUDE NAUSEA, VOMITING, LIGHT-COLORED STOOLS, UNUSAL TIREDNESS, WEAKNESS. STOMACH OR ABDOMINAL PAIN, AND LOSS OF APPETITE. NOT FOR USE BY PREGNANT OR BREASTFEEDING WOMEN. NOT FOR USE WITH ALCOHOLIC BEVERAGES. EXCESSIVE USE, OR USE WITH PRODUCTS THAT CAUSE DROWSINESS, MAY IMPAIR YOUR ABILITY TO OPERATE A VEHICLE OR HEAVY EQUIPMENT.

Product labeling and literature prominently bears the required boxed statement, "These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease."

Herbalife International of America, Inc. certifies that the information in this notice is complete and accurate, and that the Company has substantiation that the foregoing statements are truthful and not misleading.

If you have any questions, please do not hesitate to ask.

JPV:gf

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**IFRBALIFE** 

Suggested Serving: Take one tablet up to three times a day as needed.

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Supplement Facts
Serving Size: 1 Tablet
Servinas Per Container: 30

Amount Per Serving	% DV*
Total Carbohydrate 1 g	<1%
Calcium 180 mg (as dicalcium phosphate)	18%
Dried Kava Kava Extract 200 m (30% kavalactones) (root)	g t
Dried Ashwagandha Extract 50 m (1.5% withanolides) (root)	g t
Bio-absorption Complex-5 23 m	g t
Lecithin, Vitamin C (as ascorby)	palmitate),
Plant Cellulose Enzyme, Cinnam	on Powder
(bark) and Dried Black Pepper Ex	tract (from
Bioperine®) (NLT 95% piperine)	(fruit).

\* Percent Daily Values are based on a 2,000 calorie diet.

† Daily Value (DV) not established.

Other Ingredients: Microcrystalline Cellulose, Silicon Dioxide, Stearic Acid, Croscarmellose Sodium, Magnesium Stearate, Lecithin, Dextrin, Dextrose, Sodium Carboxymethylcellulose and Sodium Citrate.

Formulated Exclusively For: HERBALIFE INTERNATIONAL OF AMERICA, INC. Los Angeles, CA 90080-0210 U.S.A. MADE IN U.S.A.

30-day money-back guarantee.

STK3057US-35-00

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.625" x 3.125"

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Calcium 180 mg	18%	
(as dicalcium phosphate)		
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(30% kavalactones) (root)		
Dried Ashwagandha Extract 50 mg	†	
(1.5% withanolides) (root)		
Bio-absorption Complex-5 23 mg	†	
Lecithin, Vitamin C (as ascorbyl palmitate),		
Plant Cellulose Enzyme, Cinnamon Powder		
(bark) and Dried Black Pepper Extract (from		

\* Percent Daily Values are based on a 2,000 calone diet.

Bioperine®) (NLT 95% piperine) (fruit).

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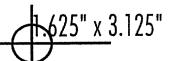
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